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10/580,029	05/19/2006	Yukako Fukuhira	Q95047	7517

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EXAMINER	
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ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,029	FUKUHIRA ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-11* is/are pending in the application.

4a) Of the above claim(s) *5 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6 and 8-10* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/4/2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Status

Applicant's response of December 15, 2008, to the species Restriction Requirement dated November 14, 2008 has been entered. Applicants' election of polylactic acid as the species of polymer, is acknowledged. The election was made without traverse.

Claims 1, 3-6 and 8-11 are pending in the application. Claims 5 and 11 stand withdrawn from further consideration, without traverse, as drawn to non-elected inventions. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01. The claims have been examined commensurate in scope with the elected invention, and the species of the invention, i.e. polylactic acid and phosphatidylethanolamine.

Claims 1, 3, 4, 6 and 8-10 are under current examination.

Withdrawn Objection to Specification

The brief description of the drawings corresponding to Figures1 and 2 was previously objected to, in the Office action dated April 2, 2008, for failing to describe items 1, 2, 3 and 4. Applicants have amended the drawings to delete items 1, 2, 3 and 4, thus obviating the ground for objection. Thus, the objection is hereby withdrawn.

New Claim Objection

Claim 6 is objected to because of the following informalities: The word "compound" should be deleted in the second line, as the corresponding word has been deleted from base claim 1.

Response & Maintained Claim Rejections - 35 USC § 103

Claims 1-4 and 8-10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Nishikawa et al. (Materials Sci. and Eng. C8-9: 495-500; 1999), in view of Watanabe et al. (Biomacromolecules 3:1109- 1114; 2002), and further in view of Sawhney, A. (U.S. Patent No.: 6,818,018; filed Aug. 14, 1998). Applicants' cancellation of claim 2 renders its rejection moot. The rejection set forth on pp. 3-4 of the previous office action dated April 2, 2008 is maintained for claims 1, 3, 4 and 8-10 for reasons of record.

Claims 1 and 6 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Nishikawa et al. (Materials Sci. and Eng. C8-9: 495-500; 1999), in view of Watanabe et al. (Biomacromolecules 3:1109- 1114; 2002), and further in view of Sawhney, A. (U.S. Patent No.: 6,818,018; filed Aug. 14, 1998), as applied to claims 1-4 and 8-10 above, and further in view of Zou et al. (U.S. Patent Publication No.: 2002/0187105; filed Feb. 1, 2002). The rejection set forth on pp. 4-6 of the previous office action dated April 2, 2008 is maintained for claims 1, 3, 4 and 8-10 for reasons of record.

The claims embrace a tissue regeneration substrate comprising a film with a honeycomb structure having an average cavity inner diameter from 0.1 to 20 μm, composed primarily of a polylactic acid polymer and phosphatidylethanolamine.

As previously indicated, Nishikawa et al. describe honeycomb-patterned thin films of amphiphilic co- polymers as cell culture substrates, that work as adhesive sites for the cells (Title and Abstract). The preparation of honeycomb films for cell culture substrates is described in section 2.2, p. 142. Nishikawa et al. describe determining the average diameter of honeycomb holes in section 2.3, p. 143, and observed that hole size of the honeycombs can be passively controlled by changing the cast volume of the polymer solution, the polymer concentration and the humidity of atmosphere, as well as the chemical properties of the polymer, exemplified by increasing the maximum diameter from 1.9 to 3.8 μm (second column, p. 144; first column p. 146).

While Nishikawa et al. do not describe including a phospholipid to their polymer film, the use of phospholipid polymers for tissue engineering was well known in the prior art, as described by Watanabe et al., teaching a porous scaffold as a cell-compatible material composed

of a phospholipid co-polymer of poly (lactic acid) for tissue engineering (Title and Abstract). Thus, curing the deficiency of a phospholipid in Nishikawa et al., and providing the motivation to include phospholipid polymers in constructing honeycomb structured films as tissue substrates. As the disclosure of both Nishikawa et al. and Watanabe et al. are directed to porous tissue regeneration substrates, it would have been obvious to include the phospholipid described by Watanabe et al. in the co-polymer film of Nishikawa et al.

Applicants respond by noting that the Examiner correctly understands that Nishikawa et al. describe honeycomb-patterned thin films of amphiphilic co-polymers as cell culture substrates, but that in the instant invention, amphiphilic polymers are excluded according to the claim amendment set forth, and a honeycomb-patterned film can never be produced from these non-amphiphilic polymers alone; and that a honeycomb-patterned film can be prepared by using even non-amphiphilic polymers in the presence of a phospholipid, which is not covalently bonded; and that this was an unexpected phenomenon and provides a basis for non-obviousness.

Applicants' arguments have been fully considered, but are not found persuasive. As an initial matter, it is unclear how amphiphilic polymers are excluded from the instant claims, as a substrate comprising polylactic acid polymer and a phospholipid would necessarily possess both a water insoluble carbon chain lipid and a polar water soluble group. The polylactic polymer contains polar water soluble groups, as lactic acid is water soluble.

With regard to the teachings of the applied prior art, Watanabe et al., described a porous scaffold as a cell-compatible material composed of a phospholipid co-polymer of poly (lactic acid) for tissue engineering (Title and Abstract), constituting an amphiphilic polymer composition. Nishikawa et al. describe honeycomb-patterned thin films of amphiphilic co-polymers as cell culture substrates, that work as adhesive sites for the cells (Title and Abstract). Applicants have stated on the record that a honeycomb-patterned film can never be produced from these non-amphiphilic polymers alone. Such is in conflict with the teachings of Applicants' own specification, that states the polymer compound composing the film of the invention is preferably a biodegradable polymer that includes polylactic acid (page 5, second paragraph); and that using a phospholipid merely allows control of the contact angle of the honeycomb structure film by adjusting the concentration of the phospholipid, in order to fabricate a more satisfactory

honeycomb structure film having a more desirable contact angle (pages 5-6, bridging). Thus, the ability of polylactic acid polymer to form a honeycomb structure was expected, as evidenced by the instant specification.

Thus, the rejections are maintained for reasons of record and the foregoing commentary.

Maintained Obviousness Type Double Patenting

Claims 1-4 and 6 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-10 and 12 of copending U.S. Patent Application No.: 10/552,685 (Patent Publication No.: 2006/0189911; commonly assigned). Applicants' cancellation of claim 2 renders its rejection moot. The rejection set forth on pp. 6-8 of the previous office action dated April 2, 2008 is maintained for claims 1, 3, 4 and 6 for reasons of record.

Applicants' deferral to respond to the rejection at the present time is considered improper and not fully responsive because it is not in compliance with 37 CFR 1.111(b), which states that "[i]n order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to the Office action. The reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. If the reply is with respect to an application, a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated. The applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action.

Conclusion

Claims 1, 3, 4, 6 and 8-10 are not allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR§1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/
Examiner, Art Unit 1633